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EXAMINER

KRUSE, DAVID H

ART UNIT PAPER NUMBER

1638

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/727,511

Applicant(s)

ARNOLD ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19, 21, 24, 26-28, 30 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19, 21, 24, 26-28, 30 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. This Office action is in response to the Amendment and Response filed 17 September 2002.
2. Claims 20, 22, 23, 25, 29 and 32 have been cancelled without prejudice as requested.
3. Those rejection not specifically addressed in this Office action are withdrawn in view of Applicant's amendment and/or arguments.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

5. Claims 30 and 31 remain rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 11 June 2002. Applicant's arguments filed 17 September 2002 have been fully considered but they are not persuasive.

Claim 30 remains indefinite for failing to adequately state positive method steps by which one could practice the claimed method. Claim 31 remains indefinite because said claim does not obviate the indefiniteness of claim 30.

Applicant argues that claim 30 recites the positive step of using the corn plant of claim 2, or its parts, as a source of breeding material in a corn plant-breeding program using plant-breeding techniques. Applicant also argues that use of a plant as a source of breeding material in a corn plant breeding program is a well known process in the art

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that forms the basis of how new corn inbreds are made (page 8, 1st paragraph of the Response). This argument is not found to be fully persuasive because at claim 31 the methods to be employed include pedigree breeding and transformation and do not necessarily produce a new corn inbred. Because of the divergent "plant breeding techniques" recited in claim 31, each of which encompass different starting materials and different method steps, it remains unclear what the metes and bounds are of both claims 30 and 31.

6. Claims 12-16, 21, 26, 27, 28 and 31 remain rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 11 June 2002. Applicant's arguments filed 17 September 2002 have been fully considered but they are not persuasive.

Applicant argues that the specification provides a description of sufficient structural characteristics of hybrid plants having inbred corn plant LH246 as one parent to satisfy the written description requirement and that the four described hybrids constitute a representative set of species describing the genus based on the shared structural characteristics of the members of the genus (paragraph spanning pages 9-10 of the Response). This argument is not found to be persuasive because Applicant states on page 3, 2nd paragraph, of the specification that a breeder of ordinary skill in the art cannot predict the final resulting lines he develops, except possibly in a very

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gross and general fashion and that the same breeder cannot produce the same line twice by using the exact same original parents and the same selection techniques. Hence, it remains unclear that Applicant was in possession of the invention as broadly claimed. See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that one must define structural features commonly possessed by members of the genus that distinguish them from others so that one skilled in the art can visualize or recognize the identity of the members of the genus, and that a definition by function does not suffice to define the genus because it is only an indication of what the material does, not what it is. In the instant case, the courts and the Office have determined that to adequately describe a plant, a deposit of such a plant is required to satisfy 35 USC 112, first paragraph. But it is the Examiner's opinion that such a deposit does not necessarily satisfy the requirement of written description for progeny of such a plant in the instant case. Hence, a description of an inbred corn plant does not adequately distinguish the genus of progeny plants from a genus of progeny plants of a different inbred corn plant, for instance, by which one of skill in the art could visualize the claimed genus.

Applicant argues that because corn plant LH246 is an inbred corn plant, all hybrid plants having LH246 as a parent will contain the same genetic contribution from LH246 and thus will be genetically distinct and identifiable from any other corn plant on this basis because LH246 is an inbred corn plant; thus all hybrid corn plants derived therefrom must inherit exactly half of the genetic material of corn plant LH246 (page 10, 2nd paragraph of the Response). This argument is not found to be persuasive because

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Applicant fails to adequately describe the degree of homozygosity of LH246 in the instant specification and it is clear from the state of the art that it would have been inhibitive for Applicant to describe at the molecular level the entire genetic structure of LH246 at the time of the invention. In such a situation, the inheritance of a corn plant produced using LH246 as a parent cannot be predictably described merely by the description of LH246.

Applicant argues that plants are fully described by way of the description of corn plant LH246 and representative transgene species, including the accompanying phenotypic effect of the transgenes (paragraph spanning pages 10-11 of the Response). Applicant also argues that the examples described constitute a representative set of species supporting a description of the genus of transformed LH246 plants and to conclude otherwise would limit Applicants to that subject matter described *ipsis verbis* in the specification (page 11, 2nd paragraph of the Response). This argument is not found to be persuasive because the “examples” in the specification are prophetic and do not clearly indicate Applicant was in possession of any transformed LH246 plants. In addition, to adequately describe the claimed genus, one of skill in the art must be able to visualize such a genus based on the written description in the specification. In the instant case, one of skill in the art could not visualize the genus of transformed LH246 corn plants as broadly claimed.

7. Claims 1-19, 21, 24, 26, 27, 28, 30 and 31 remain rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with

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which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 11 June 2002. Applicant's arguments filed 17 September 2002 have been fully considered but they are not persuasive.

Applicant states that a declaration certifying that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809 will be provided (page 12, 3rd paragraph of the Response). The Examiner maintains the instant rejection until such time as Applicant has provided an adequate declaration. In order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (i) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (ii) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (iii) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (iv) a test of the viability of the biological material at the time of deposit (see 37 CFR § 1.807); and,
- (v) the deposit will be replaced if it should ever become inviable.

At the present time, Applicant has not provided assurance of irrevocable removal of all restrictions to the public upon granting of the patent as outlined above. The Examiner notes the perfection of the actual deposit may be deferred until prior to payment of the issue fee of the patent, but the affidavit or declaration cannot be deferred in response to this rejection.

8. Claims 26-28 remain rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 11 June 2002. Applicant's arguments filed 17 September 2002 have been fully considered but they are not persuasive.

Applicant argues that all that is required to satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, is that Applicants teach one reasonably skilled in the art how to make and use the claimed invention without undue experimentation (page 13, 1st paragraph of the Response). This argument is not found to be persuasive because Applicant has failed to adequately teach one of reasonable skill in the art how to make and use the corn plant LH246 transformed with any transgene as broadly claimed.

Applicant argues that Applicants must only teach one of skill in the art to make and use the invention and that the specification describes numerous plant transformation techniques that are known in the art (page 13, 2nd paragraph of the

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Response). This argument is not found to be persuasive, because while Applicant has taught one of skill in the art how to make and use a number of transgenic plants produced from corn line LH246, Applicant fails to teach one of skill in the art how to make and use all transgenic plants produced from corn line LH246.

Applicant argues that the specification describes numerous coding and regulatory sequences for transformation into corn plant LH246 and that this teaching is more than adequate to teach one of skill in the art to introduce one or more transgenes into corn variety LH246 (paragraph spanning pages 13-14 of the Response). This argument is not found to be persuasive because Applicant has failed to adequately teach one of skill in the art how to make and use a transgenic LH246 corn plant as broadly claimed because Applicant has failed to teach one of skill in the art the use of any transgenic LH246 corn plant.

The following amendments would obviate the rejections under 35 USC § 112, first paragraph:

Cancel claims 12-16, 21, 26, 27 and 28.

Submit new claims 33-41 below (support for said claims can be found in the specification, pages 22-29).

-- New claim 33. A method of producing an herbicide resistant corn plant comprising transforming the corn plant of claim 2 with a transgene that confers herbicide resistance.

New claim 34. An herbicide resistant corn plant produced by the method of claim 33.

New claim 35. A method of producing an insect resistant corn plant comprising transforming the corn plant of claim 2 with a transgene that confers insect resistance.

New claim 36. An insect resistant corn plant produced by the method of claim 35.

New claim 37. A method of producing a disease resistant corn plant comprising transforming the corn plant of claim 2 with a transgene that confers disease resistance.

New claim 38. A disease resistant corn plant produced by the method of claim 37.

New claim 39. A method of producing a corn plant with decreased phytate content comprising transforming the corn plant of claim 2 with a transgene encoding phytase.

New claim 40. A corn plant with decreased phytate content, produced by the method of claim 39.

New claim 41. A method of producing a corn plant with modified fatty acid or carbohydrate metabolism comprising transforming the corn plant of claim 2 with one or more transgenes encoding a protein selected from the group consisting of stearyl-ACP desaturase, fructosyltransferase, levansucrase, alpha-amylase, invertase, and starch branching enzyme.

New claim 42. A corn plant produced by the method of claim 41. –

Claim Rejections - 35 USC § 102/103

9. Claims 12-16 remain rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Foley (U.S. Patent

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5,059,745). This rejection is repeated for the reason of record as set forth in the last Office action mailed 11 June 2002. Applicant's arguments filed 17 September 2002 have been fully considered but they are not persuasive.

Applicant argues that the identical invention must be shown in as complete detail as is contained in the claim (page 14, 4th paragraph of the Response). Applicant argues that to the extent that alleged unexpressed inherent characteristics form the basis of an anticipation rejection, it is noted that these characteristics must necessarily flow from the disclosure, and that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill (page 15, 1st paragraph of the Response). The Examiner response that Applicant admits that breeder's selection occurs in unique environments, with no control at the DNA level using conventional breeding procedures and with millions of different possible genetic combinations being generated (page 3, 2nd paragraph of the specification). The disclosure of both Applicant and Foley are based on gross characteristics of the respective inbred corn lines and not detailed disclosures of said corn lines. In the instant case, given the limited ability of either Foley or Applicant to teach all inheritable traits of their respective inbred corn line, and the availability of a myriad of other inbred corn plants, the instant claims would inherently encompass hybrid corn seed and plants produced by crossing the LH195 inbred corn plant of Foley with another inbred corn plant, and such hybrid corn seed and plants would be indistinguishable to one of ordinary skill in the art at the time of Applicant's invention.

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Applicant argues that there is no motivation or suggestion in the prior art to arrive at the invention, or rationale for such a motivation, and that the rejection relies on an obvious to try type rationale. Applicant argues that one of skill in the art would have no reasonable expectation of success in selecting a second inbred corn plant to arrive at the invention, and that the prior art does not teach or suggest all of the claim limitations (paragraph spanning pages 15-16 of the Response). The Examiner responds that Foley suggests crossing the taught LH195 inbred with any other inbred corn line at claim 5. In addition, the instant claims do not provide any limitations by which one of ordinary skill in the art at the time of Applicant's invention could distinguish any hybrid corn plant produced from the LH195 inbred of Foley from Applicant's LH246 inbred line. See *In re Best*, 195 USPQ 430 (CCPA 1977) which teaches that where the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See also, *In re Brown and Saffer*, 173 USPQ 685 (CCPA 1972) which teaches that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

David H. Kruse, Ph.D.
17 March 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

